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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,989	02/05/2004	Paul A. Iaizzo	P0008965.00/LG10126	5392

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EXAMINER	
BERTRAM, ERIC D	

ART UNIT	PAPER NUMBER
3766	

NOTIFICATION DATE	DELIVERY MODE
12/21/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/772,989	IAIZZO ET AL.	
	Examiner	Art Unit	
	Eric D. Bertram	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,7,11,12,18,20,21,23,24,26-28,30-35 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *3,4,7,11 and 12* is/are allowed.

6)☒ Claim(s) *18,20,21,23,24,26,27,30-35 and 37* is/are rejected.

7)☒ Claim(s) *28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 10/12/2010 have been fully considered but they are not persuasive. Regarding claims 18, 20, 23, 24, 27, 30-32 and 35, the applicant argues that the Examiner proposes that "either (1) the projecting edges 25, 81 of Lampadius (which have been allegedly equated to the claimed guard) would be modified to have smaller diameters than the guide catheters 23, 79 or (2) the guide catheters 23, 79 of Lampadius (which have been allegedly equated to the claimed delivery catheter) would be modified to have larger diameters than the projected edges 25, 81." However, the Examiner has not proposed either modification. Instead, the Examiner simply proposes adding the catheter of Starksen to the existing arrangement of Lampadius. The delivery catheter 23,79 of Lampadius is still necessary to push the edges 25,81 in order to propel catheter through the larger catheter of Starksen. Furthermore, Starksen specifically teaches that his delivery catheter is designed to be used with "conventional electrical leads so that the actual design of the pacemaker system need not be changed in any way" (Col. 2, lines 4-7). The combination of the external catheter of Starksen with the lead and delivery/pushing catheter design of Lampadius would not interfere in the intended purpose or workings of Lampadius. The combination of Starksen and Lampadius, and thus the rejections of claims 18, 20, 23, 24, 27, 30-32 and 35, is still considered proper.

2. Regarding claims 21, 33 and 34, the applicant merely relied on the arguments presented against the combination of Lampadius and Starksen, which are addressed

above. The 35 USC 103(a) rejections of claims 21, 33 and 34 are still considered proper.

3. The rejection of claim 26, rejected in paragraph 12 of the previous office action, was never addressed by the applicant. As such, this rejection is still considered proper.

4. Regarding new claim 37, Lampadius clearly discloses a glue segment that is not encapsulated. As seen in figure 1, glue segment 15 can freely move through openings 17 at all times. The rejection will be further outlined below.

5. Applicant's arguments filed with respect to claim 28 have been fully considered and are persuasive. The rejection of claim 28 has been withdrawn.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 10/12/2010 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 18, 20, 23, 24, 26, 27, 30-32, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius in view of Starksen.

11. Regarding claims 18, 27, 30 and 32, Lampadius discloses a medical lead as shown in figures 1-3. The figures all show the distal end of the lead body 23, which includes a glue segment 67 disposed around a tip electrode 65. The glue segment comprises a tissue adhesive encapsulated in a biocompatible capsule (i.e., "plastic ampul") that is formulated to rupture when said lead is urged against a treatment site, liberating the tissue adhesive, and affixing the lead body to the treatment site (see the second to last paragraph in the translation). Furthermore, the distal end 81 is considered a guard for the glue segment, since it extends out past the sides of the glue segment, much like the guard 18 shown in figure 1 of the applicant's specification, and also extends out past the distal end of the lead body, and would prevent the glue

segment from contacting a wall of a catheter lumen as the lead is advanced therethrough. As such, the guard has a larger diameter than the lead body of the lead.

12. However, while Lampadius does disclose the use of a catheter 23,79 for insertion of the lead, Lampadius is silent as to the guard having a smaller diameter than a catheter so that the lead may be implanted by advancing the lead through the catheter. Attention is directed to the secondary reference of Starksen, which discloses a guide catheter 10 with a lumen wide enough to accommodate cardiac leads (Col. 4, lines 5-12). After placing the catheter in the proper location, and utilizing balloon 18 to protect the heart tissue (Col. 4, lines 29-40), the lead will be advanced through the catheter to a treatment site (Col. 5, lines 58-65). Therefore, the Examiner proposes adding the catheter of Starksen to the existing arrangement of Lampadius since Starksen specifically teaches that his delivery catheter is designed to be used with "conventional electrical leads so that the actual design of the pacemaker system need not be changed in any way" (Col. 2, lines 4-7). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify Lampadius to utilize a catheter as described in Starksen, since this is a known apparatus for the introduction of leads in the heart and would have allowed an electrical lead to be properly implanted at a treatment site (see Col. 2, of Starksen). Additionally, the combination of the external catheter of Starksen with the lead and delivery/pushing catheter design of Lampadius would not interfere in the intended purpose or workings of Lampadius. Furthermore, it would be obvious that in order to achieve this, the guard would have to have a smaller diameter than the inner diameter of the catheter.

13. Regarding claim 20, Lampadius discloses the adhesive may be a 2-butyl cyanoacrylate (i.e., "Butyl-2-zyanoakrylat").

14. Regarding claims 23 and 24, Lampadius discloses the glue segment is torus-shaped, which is both annular and tubular.

15. Regarding claims 26 and 31, Lampadius discloses that the adhesive could be delivered through a lumen in the lead and forced through ports 17 (see figure 1). As the adhesive is forced through the ports, two dots will inherently form.

16. Regarding claim 35, an implantable medical device must inherently be connected to the lead in order to apply the electrical energy.

17. Regarding claim 37, Lampadius clearly discloses an embodiment with a glue segment that is not encapsulated. As seen in figure 1, glue segment 15 can freely move through openings 17 at all times. The rejection will be further outlined below.

18. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius and Starksen in view of Munch et al. (US 6,463,335, hereinafter Munch). While Lampadius discloses the applicant's basic invention, including a tissue adhesive for securing a medical lead to the heart, Lampadius is silent as to using a fibrin glue as the tissue adhesive. Attention is directed to the secondary reference of Munch, which discloses a electrode secured to the heart by using a fibrin glue (Col. 20, lines 1-32). Therefore, it would have been obvious to one of ordinary skill in the art to substitute fibrin glue for the n-butyl cyanoacrylate of Lampadius since both are known biocompatible tissue adhesives, and both would work equally well in securing a lead to the heart.

19. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius and Starksen in view of Sigg et al. (US 6,931,286, hereinafter Sigg). Lampadius, as modified above, discloses the applicant's basic inventive concept with the exception of the catheter including mapping electrodes. Column 5, lines 20-30 of Sigg describes the use of a mapping catheter during the implantation of electrical leads. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Sigg et al. to modify the system of Lampadius by adding a lumen in the lead in order to apply the tissue adhesive to the application site and to also include mapping electrodes in order to locate a desirable application site.

20. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius and Starksen in view of Igo et al (US 6,666,844, hereinafter Igo). Lampadius, as modified above, disclose the applicant's basic inventive concept with the exception of the catheter having a suction capacity. Column 6, line 65 of Igo discloses a passage 120 in the catheter that is to supply a vacuum to withdraw fluid. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Igo to modify the system of Lampadius, as modified, by adapting the catheter to apply suction to a tissue site in order to remove excess moisture from the site.

Allowable Subject Matter

21. Claims 3, 4, 7, 11 and 12 are allowed.

22. Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is (571)272-3446. The examiner can normally be reached on Monday-Thursday from 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric D. Bertram/
Primary Examiner, Art Unit 3766